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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/544,112

08/02/2005

Takanori Miyoshi

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EXAMINER

CHRISS, JENNIFER A

ART UNIT

PAPER NUMBER

1786

NOTIFICATION DATE

DELIVERY MODE

08/12/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/544,112	Applicant(s) MIYOSHI ET AL.	
	Examiner JENNIFER A. CHRISS	Art Unit 1786	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 4, 6 - 8 and 10 - 13 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 4, 6 - 8 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.
2. In view of Applicant's submission of the translation of the Japanese priority documents, JP 2003-034779 and JP 2003-094176, which perfects Applicant's claim to priority, the Examiner withdraws the 35 USC 103(a) rejection as being unpatentable over the Technical Paper entitled "Technique Paper for Wet-Spinning Poly(L-lactic acid) and Poly(DL-lactic-co-glycolide) Monofilament Fibers".
3. After an updated search, additional art has been found which renders the invention as currently claimed unpatentable for reasons herein below.

Claim Rejections - 35 USC § 103

4. Claims 1 – 4, 6 – 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. (US 6,596,296).

Nelson et al. is directed to a three-dimensional matrix of biodegradable polymers capable of controlled delivery of therapeutic agents (Abstract).

As to claim 1, Nelson et al. teach that the matrix can comprise non-woven scaffolding as shown in Figure 2 (column 8, lines 30 - 55) made of biodegradable polymers such as polylactic acid, polycaprolactone, polyglycolic acid (column 9, lines 65 - 68 and column 10, lines 1 - 10). The polymer further contains a therapeutic agent (columns 10 - 17). Among the therapeutic agents that can be included in the fiber are monosaccharides and other biological molecules of interest (column 8, lines 15 - 30).

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Nelson et al. teach that the fiber can have a diameter of less than 20 microns (column 3, lines 20 – 25). In Example 1, Nelson et al. discusses that the polymer can be dissolved in solvent such as methylene chloride or chloroform (column 17, lines 40 - 65). Nelson et al. note that the fiber surface texture of the finished fiber can be controlled by appropriate choices of solvent and polymer systems and can create fibers as shown in Figures 11A - 11C (column 18, lines 50 – 65).

Although Nelson et al. do not specifically teach the use of particular monosaccharides, it would have been obvious to one of ordinary skill in the art to select a common form of monosaccharide, specifically glucose (MW = 180 g/mol) which has hydroxyl groups as required by Applicant as the organic compound motivated by the desire to create a three-dimensional matrix of biodegradable polymers having a suitable therapeutic agent depending on the desired end use.

Nelson teaches the claimed invention above but fails to teach that the fiber porosity is at least 5%. It is reasonable to presume that the porosity of at least 5% is inherent to the fiber of the paper. Support for said presumption is found in the use of like materials (i.e. a porous fiber and nonwoven made therefrom comprising porous fibers made of PLA, etc. having a low molecular weight therapeutic agent having hydroxyl groups) which would result in the claimed property. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed properties would obviously have been present once the product of the paper is provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977). Reliance upon

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inherency is not improper even though the rejection is based on Section 103 instead of 102. *In re Skoner*, et al. (CCPA) 186 USPQ 80.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

6. The M.S. Thesis of A. Romero-Sanchez entitled *Biodegradable fibers fabricated by a wet-spinning technique* from the Department of Biomedical Engineering, University of Texas at Arlington, Arlington, TX, 1998 appears to be pertinent to applicant's disclosure as the previously applied Technical Paper entitled "Technique Paper for Wet-Spinning Poly(L-lactic acid) and Poly(DL-lactic-co-glycolide) Monofilament Fibers" cites the M.S. thesis in the Materials and Method section of the paper and the paper indicates that hundreds of fibers have been produced with a wide range of physical and mechanical properties over the 6 years prior to the paper. The Thesis is available at the University of Texas Southwestern Medical Center at Dallas in their South Campus Library.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER A. CHRISS whose telephone number is (571)272-7783. The examiner can normally be reached on Monday - Friday, 8:30 a.m. - 6 p.m., first Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Tarazano can be reached on 571-272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer A Chriss/
Primary Examiner, Art Unit 1786

/J. A. C./
Primary Examiner, Art Unit 1786